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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/046,504 | 10/19/2001 | Steven J. Siegel | P-9565-US | 3358 |
| 49443 7590 04/17/2007 PEARL COHEN ZEDEK LATZER, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036 | | | EXAMINER FUBARA, BLESSING M | |
| | | | ART UNIT 1618 | PAPER NUMBER |
| | | | MAIL DATE 04/17/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|---|---------------------------------------|--------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 10/046,504 | Applicant(s) SIEGEL ET AL. | |
| | Examiner Blessing M. Fubara | Art Unit 1618 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: _____.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

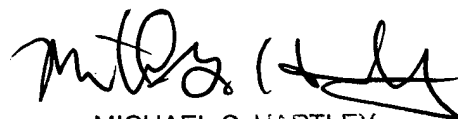
REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's argument is centered on the contention that the polymer of Mao has phosphate group that influences the degradation pattern of the polymer and that the consisting essentially of language excludes the polymer of Mao; that a range of 1-65% for the active agent is broader than the claimed range of 20-40%. The 1-65% haloperidol or active agent encompasses the claimed 20-40% and points within the disclosed range touches the claimed range. While Mao teaches the use of OH terminated copolymer derived from lactide and glycolide (column 13, lines 3,4), applicant's argument that Mao does not disclose the use of unmodified prepolymers is not persuasive since the claimed invention does not specifically claim or un-claim modified or unmodified lactide or glycolide. Also, Mao lists clozapine, haloperidol and risperidone for the antipsychotic drugs (column 20, lines 1 and 2) and as such the listing of the three drugs under antipsychotic does not represent laundry list of active agents. In response to applicant's argument on the transitional phrase, "consisting essentially of," it is noted as has been explained in the final office action, the consisting essentially of language only excludes components that materially affect the basic and novel characteristic of the invention. In the present case, the basic and novel characteristic of the claimed invention is not materially affected by the presence of phosphate with lactide-glycolide copolymer because the device of the Mao is biodegradable, non-toxic and releases antipsychotic drug, haloperidol, when present. Furthermore, applicant does not make clear in the instant specification what applicant regards as constituting a material change in the basic and novel characteristics of the invention as it applies to the transitional phrase "consisting essentially of" for purposes of its patent.

BF



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER